PA[T] [I]T COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 30 October 2000 (30.10.00)	
International application No. PCT/IE00/00034	**Applicant's or agent's file reference** P7923.WO
International filing date (day/month/year) 20 March 2000 (20.03.00)	**Priority date** (day/month/year) 18 March 1999 (18.03.99)
Applicant ROSNEY, Damien et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

11 September 2000 (11.09.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Zakaria EL KHODARY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

TENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P7923.WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IE00/00034	20/03/2000	18/03/1999
International Patent Classification (IPC) or national classification and IPC A61B17/34		
Applicant GAYA LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11/09/2000	03.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized officer Hansen, S Telephone No. +49 30 25901 628

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00034

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

4-7	as originally filed			
1,1a-1b,2,3	as received on	09/04/2001	with letter of	09/04/2001

Claims, No.:

1-12	as received on	09/04/2001	with letter of	09/04/2001

Drawings, sheets:

1/2,2/2	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
   see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-12
	No:	Claims	1-3
Inventive step (IS)	Yes:	Claims	
	No:	Claims	4-12
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations
   see separate sheet

Re Item I

The amendments filed with the letter dated 09.04.01 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
The applicant has added the features "..fixing means (5,6) for attaching the device to a patient's skin ...the fixing means including a ring" and "the positioning of the ring (5) retracting the body cavity engagement means to defin ..." to claim 1. From the originally filed specification (cf. page 4, lines 19-29) it appears that the fixing means for attaching the device to the skin is a web and that the engagement means is identical with the anchor ring (5).
Consequently, this report had to be established on the basis of the originally filed claim 1.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-5 366 478,
D2: GB-A-2 275 420,
D3: US-A-5 634 937,
D4: US-A-5 636 645,
D5: US-A-5 514 133.

2. Document D1 discloses a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having:
body cavity engagement means (anchor ring 20) for insertion into the incision to locate the device in position;
fixing means (fixing ring 19) for attaching the device to a patients skin; and
sealing means (toroid cell 11,13,15) connected between the body cavity engagement

means (20) and the fixing means (19), the sealing means being formed to prevent substantial leakage of gas from the body cavity on inflation when in an operative position and formed to mould to a substantial portion of a surgeons hand or surgical instrument on insertion in an operating position.

Consequently, the subject-matter of claims 1-3 is not novel (Article 33(2) PCT).

3. Dependent claims 2-12 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), the reasons being as follows:

3.1 The features of dependent claims 4 and 5 have already been employed for the same purpose in similar devices, see documents D3 (claim 1) resp. D2 (page 10, lines 16-21). It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claims 4 and 5.

3.3 In claims 6-12 only a slight constructional change in the device is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen (see also D1-D5). Consequently, the subject-matter of claims 9-14 also lacks an inventive step.

A SURGICAL DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patients abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

United States Patent Specification No. US-A-5 366 478 discloses a sealing device for endoscopic surgical procedures. In one embodiment, the device has two inflatable toroidal sections connected by a transition section. The device is partially inserted into an

abdominal opening in a deflated state, and then inflated to provide a seal for obstructing the passage of gas from the abdominal cavity during endoscopic surgery. Endoscopic instruments, or alternatively, the surgeon's hand, can penetrate through the lumen of the toroidal sections of the device. The lumen then conforms to the shape of the instrument or hand passed through it to maintain an adequate seal.

United Kingdom Patent Specification No. GB 2 275 420 discloses a medico-surgical system for access to a hollow viscus includes a member adapted to extend through an opening in the skin into the viscus of the patient so that one end of the member is located within the viscus and the other end terminates adjacent the skin. Balloons are provided for retaining the one end of the member within the viscus. The balloons also act as sealing means, adapted to seal the opening whilst allowing intermittent access to the viscus by means of a catheter.

United States Patent Specification No. US 5 634 937 discloses a skin seal or trocar stabilizer with an inflatable balloon in the shape of a dumbbell, where the balloon may be stored within a cannula for easy placement in an incision and inflated to deploy the balloon inside the body, and a portion of the balloon expands inside the cannula, whereby medical instruments may be passed through the skin seal into a laparoscopic work space while the balloon is inflated, thereby allowing the use of normal short surgical instruments during laparoscopic procedures and during insufflation.

United States Patent Specification No. US 5 636 645 discloses a method of performing surgery, which comprises making a first opening in a body cavity wall to permit entry of a surgeon's gloved hand. Next, the surgeon's gloved hand is placed into the body cavity through the opening and a gas is infused into the body cavity through the first opening or through the second opening. The surgical procedure is performed and the surgeon's hand is removed from the body cavity. The surgeon's gloved hand can be provided with a sealant for engaging the sides or surrounding tissue of the first opening, thereby creating a substantially gas-tight seal. The sealant can comprise an inflatable member circumferentially disposed around the forearm portion of the surgeon's glove or can

comprise a disk having an adhesive on the distal surface for sealingly engaging the surrounding tissue of an opening in a body cavity wall.

United States Patent Specification No. US 5 514 133 discloses an endoscopic surgical apparatus for enabling a surgeon to access directly the surgical site during an endoscopic procedure. This apparatus includes an opening extending longitudinally through the apparatus and being configured and dimensioned to receive a hand therethrough. A first plate engages against the outer surface of the abdominal wall. A second plate is spaced from the first plate and is movable between a first position and a second position wherein the second plate is in close cooperative alignment with the inner surface of the abdominal wall. An adjustment member is mounted to the second plate and actuates movement of the second plate between its first position and its second position. A first sealing member inhibits the flow of gas through said opening and is formed by a pair of overlapping seals. A flexible sleeve extends between the first and second plates and adjusts in length to accommodate various thicknesses of the abdominal wall. The sleeve also creates an access port for the passage of objects through the abdominal wall.

Accordingly, the present invention provides a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device having:-

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin; characterized in that

the fixing means including a ring; characterized in that

the body cavity engagement means is adjustable by the positioning of the ring; and

the positioning of the ring retracting the body cavity engagement means to define an access port and create a sealing means between the incision and the body cavity engagement means;

the ring having an associated connector ring for receiving additional seals or medical instruments; and

additional sealing means incorporating a foam shell to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

Preferably, the ring is an anchor ring formed for insertion into the incision.

Ideally, the sealing means is provided by a toroid cell formed to engage the incision between the fixing means and the body cavity engagement means.

Preferably, the cell forms a bladder through which the surgeon may access the body cavity, the bladder being filled with a viscous or semi-viscous liquid.

Preferably, the bladder is filled with saline, gel or foam.

The foam shell may be formed in two parts, or as a single part partially divided along one axis, the parts being movable relatively to allow a surgeon access to the body cavity.

In one arrangement the foam shell is formed by a plurality of individually disengageable layers. In this way the surgeon can adjust the height of the foam shell in response to particular needs by adding or removing foam layers. Thus a single device may be used on abdomens of varying thickness, enhancing flexibility of application. Furthermore, the rigidity created by the induced gas and foam apron allows for hand insertion and withdrawal without the aid of an assistant or requiring the surgeon to use the other hand. Additionally, the external valve created by the inclusion of a foam shell is enhanced by the pressure of the induced gas passing up between the double walled tube and acting to force the opposing faces of film together outside the patients abdominal cavity.

Preferably, the sealing means further incorporates a distal valve for insertion into the body cavity.

Ideally, the distal valve includes a mechanical seal.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, various embodiments of a surgical device in accordance with the invention, in which:-

Fig. 1 is a top view of a surgical device in accordance with the invention;

Fig. 2 is a sectional view of the surgical device of Fig. 1 in the direction of the arrows A-A;

Fig. 3 is a sectional view similar to that shown in Fig. 2 showing the device in an inoperative position with a surgeon's hand approaching;

CLAIMS:

1. A surgical device (1) for use in minimally invasive surgery of the type using an inflated body cavity (2) accessible to a surgeon through an access port, defined by the device (1), surrounding an incision in a patient's body, the device (1) having: -

body cavity engagement means (5) for insertion into the incision to locate the device (1) in position;

fixing means (5,6) for attaching the device to a patient's skin;

the fixing means including a ring; characterized in that

the body cavity engagement means is adjustable by the positioning of the ring (5); and

the positioning of the ring (5) retracting the body cavity engagement means to define an access port and create a sealing means between the incision and the body cavity engagement means;

the ring having an associated connector ring (7) for receiving additional seals or medical instruments; and

additional sealing means incorporating a foam shell (28) to prevent substantial leakage of gas from the body cavity (2) on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

2. A surgical device as claimed in Claim 1, in which the ring is an anchor ring (5) formed for insertion into the incision.

3. A surgical device as claimed in any one of the preceding claims, in which the sealing means is provided by a toroid cell (8) formed to engage the incision between the fixing means (6) and the body cavity engagement means (5).

4. A surgical device as claimed in Claim 3, in which the cell (8) forms a bladder through which the surgeon may access the body cavity, the bladder being filled with a viscous or semi-viscous liquid.

5. A surgical device as claimed in Claim 4, in which the bladder is filled with saline, gel or foam.

6. A surgical device as claimed in Claim 1, in which the foam shell (28) is provided as a single block defining a passageway therein, to allow communication between the exterior and the cavity (2).

7. A surgical device as claimed in Claim 1, in which the foam shell (28) is formed in two parts, or as a single part partially divided along one axis, the parts being movable relatively to allow a surgeon access to the body cavity (2).

8. A surgical device as claimed in Claim 1, Claim 6 or Claim 7, in which the foam shell (28) is formed by a plurality of individually disengageable layers, so that the surgeon can adjust the height of the foam shell in response to particular needs by adding or removing foam layers whereby a single device (1) may be used on abdomens of varying thickness, enhancing flexibility of application.

9. A surgical device as claimed in Claim 8, in which the rigidity created by the induced gas and foam apron allows for hand insertion and withdrawal without the aid of an assistant or requiring the surgeon to use the other hand.

10. A surgical device as claimed in Claim 6, 7 or 8, in which the external valve created by the inclusion of the foam shell is enhanced by the pressure of the induced gas passing

up between the double walled tube and acting to force the opposing faces of film together outside the patients abdominal cavity.

11. A surgical device as claimed in any one of the preceding claims in which the sealing means further incorporates a distal valve (31) for insertion into the body cavity.

12. A surgical device as claimed in Claim 11, in which the distal valve (31) includes a mechanical seal (32).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
P7923.WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/IE 00/ 00034	20/03/2000	18/03/1999
Applicant		
GAYA LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   A SURGICAL ACCESS DEVICE

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]/IE 00/00034

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 366 478 A (CANDADAI RAMESH S ET AL) 22 November 1994 (1994-11-22) the whole document ---	1-3,5
X	GB 2 275 420 A (GAUNT DAVID RAMON ;GLICKMAN SCOTT (GB)) 31 August 1994 (1994-08-31) page 10, line 16 - line 21 ---	1,7,8
X	US 5 634 937 A (MOLLENAUER KENNETH H ET AL) 3 June 1997 (1997-06-03) abstract; claim 1; figure 17 ---	1,5-7
X	US 5 636 645 A (OU HONZEN) 10 June 1997 (1997-06-10) column 5, line 38 -column 9, line 6; figures 4-10 ---	1,3,6,7
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 July 2000	04/08/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 00/00034

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 514 133 A (STEIN H DAVID ET AL) 7 May 1996 (1996-05-07) the whole document	1,4
X	US 5 803 921 A (BONADIO FRANK) 8 September 1998 (1998-09-08) abstract; figures 1,9,23	1
A	US 5 524 644 A (CROOK BERWYN M) 11 June 1996 (1996-06-11) abstract; figures 3-6	1
A	US 5 741 298 A (MACLEOD CATHEL) 21 April 1998 (1998-04-21) abstract; figure 2	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
IE 00/00034

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5366478 A	22-11-1994	NONE	
GB 2275420 A	31-08-1994	NONE	
US 5634937 A	03-06-1997	WO 9636283 A	21-11-1996
		US 5964781 A	12-10-1999
US 5636645 A	10-06-1997	NONE	
US 5514133 A	07-05-1996	NONE	
US 5803921 A	08-09-1998	IE 940150 A	04-10-1995
		IE 940613 A	04-10-1995
		IE 950055 A	07-08-1996
		AT 164303 T	15-04-1998
		AU 695770 B	20-08-1998
		AU 1717395 A	04-09-1995
		BR 9506817 A	09-09-1997
		CA 2183064 A	24-08-1995
		CN 1144471 A	05-03-1997
		CZ 9602404 A	16-04-1997
		DE 69501880 D	30-04-1998
		DE 69501880 T	23-07-1998
		EP 0744922 A	04-12-1996
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		ES 2115365 T	16-06-1998
		FI 963226 A	17-10-1996
		HU 76016 A,B	30-06-1997
		WO 9522289 A	24-08-1995
		JP 9509079 T	16-09-1997
		NO 963421 A	14-10-1996
		NZ 279907 A	26-06-1998
		PL 315939 A	09-12-1996
		RU 2137453 C	20-09-1999
		ZA 9501378 A	24-10-1995
US 5524644 A	11-06-1996	NONE	
US 5741298 A	21-04-1998	US 5947922 A	07-09-1999

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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A SURGICAL ACCESS DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patients abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin; and

sealing means connected between the body cavity engagement means and the fixing means, the sealing means being formed to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould to a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

Preferably, the body cavity engagement means is provided by an anchor ring formed for insertion into the incision.

Preferably, the fixing means is provided by an adhesive web or fixing ring.

In one arrangement, the fixing means has an associated connector ring for receiving additional seals or medical instruments.

Ideally, the sealing means is provided by a toroid cell formed to engage the incision between the fixing means and the body cavity engagement means.

Preferably, the cell forms a bladder through which the surgeon may access the body cavity, the bladder being filled with a viscous or semi-viscous liquid.

Preferably, the bladder is filled with saline, gel or foam.

In one embodiment, the sealing means incorporates a foam shell formed for covering the incision.

Preferably, the foam shell is formed in two parts, or as a single part partially divided along one axis, the parts being movable relatively to allow a surgeon access to the body cavity.

In one arrangement the foam shell is formed by a plurality of individually disengageable layers. In this way the surgeon can adjust the height of the foam shell in response to particular needs by adding or removing foam layers. Thus a single device may be used on abdomens of varying thickness, enhancing flexibility of application. Furthermore, the rigidity created by the induced gas and foam apron allows for hand insertion and withdrawal without the aid of an assistant or requiring the surgeon to use the other hand. Additionally, the external valve created by the inclusion of a foam shell is enhanced by the pressure of the induced gas passing up between the double walled tube and acting to force the opposing faces of film together outside the patients abdominal cavity.

Preferably, the sealing means further incorporates a distal valve for insertion into the body cavity.

Ideally, the distal valve includes a mechanical seal.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, various embodiments of a surgical device in accordance with the invention, in which:-

Fig. 1 is a top view of a surgical device in accordance with the invention;

Fig. 2 is a sectional view of the surgical device of Fig. 1 in the direction of the arrows A-A;

Fig. 3 is a sectional view similar to that shown in Fig. 2 showing the device in an inoperative position with a surgeon's hand approaching;

Fig. 4 is a sectional view as shown in Figs. 2 and 3 showing the device in an operating position with the surgeons hand in place;

Fig. 5 is a plan view of and alternative surgical device in accordance with the invention;

Fig. 6 is a front view of the surgical device of Fig. 5; and

Fig. 7 is an end view of the surgical device of Figs. 5 and 6.

Referring to the drawings, and initially to Figs. 1 to 4, there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by the device 1, surrounding an incision in a patient's abdominal wall 3.

In more detail, the device 1 has a body cavity engagement means provided by an anchor ring 5 for insertion into the incision to locate the device 1 in position. The device 1 is held in position on the patient's skin out side the body by a fixing means provided in this case by an adhesive web 6. The ring 5 and web 6 ensure that the device 1 is securely fixed in position and surround the incision. It will be noted that the web may be replaced by any functional equivalent to secure the device in position.

The web 6 has an associated connector ring 7 for receiving additional seals to prevent loss of pressure from the cavity 2. The connector ring 7 may also be used for holding or guiding medical instruments into position over or in the incision.

The device 1 has a sealing means, provided in this embodiment of the invention, by a saline filled toroid cell 8 connected between the anchor ring 5 and the web 6. The cell 8 is formed to prevent substantial leakage of gas from the body cavity 2 on inflation when in an

inoperative position see Figs. 2 and 3. The cell 8 is also formed to mould to a substantial portion of a surgeon's hand or surgical instrument when in an operating position (see Fig. 4). The cell 8 is also formed to allow for the removal of operative tissue when in an operating position with or without pneumoperitoneum established.

It will be noted that the cell may be filled with any suitable material and represents a significant improvement over prior art devices, which are inflated with air. The use of a liquid such as a sealed saline bladder improves hygiene around the wound and responds more quickly to a movement by a surgeon's hand. Additionally the invention overcomes problems associated with inflatable bladders, which will leak air if under inflated or be overly restrictive to movement if over inflated.

It will further be noted that the sealing means is described as a toroid or donut shaped cell, but that it could be equally provided as a lip shaped or elliptical cell tapering slightly at either end.

In use, an incision is made in the abdominal wall 3 and the anchor ring 5 passed through the incision into the cavity 2. The anchor ring 5 is moved when in the cavity 2 such that the ring 5 surrounds the incision. The web 6 is then attached to the patients skin to fix the device 1 in position with the cell 8 being connected between the web 6 and the ring 5 and engaging the portions of the abdominal wall 3 exposed by the incision. The cell 8 seal the incision and the abdominal cavity 2 may be inflated as required by the surgeon to an inoperative position Fig.2. The surgeon can gain access to the cavity 2 losing a minimum of gas pressure by passing a hand or instrument through the center of the toroid or donut shaped cell 8. When the hand or instrument is in the operating position (Fig. 4) the cell moulds to the hand or instrument to prevent loss of pressure.

Referring now to Figs. 5 to 7 there is illustrated a further surgical device in accordance with the invention indicated generally by the reference numeral 20, in which parts similar to those identified with reference to Figs. 1 to 4 are identified by the same reference numerals generally. In this embodiment the sealing means is in two sections. A foam shell 28 is in this case formed in two parts to envelop the incision site. It will be understood that

the foam shell may equally be provided as a single part, divided or split along an axis. The parts of the shell 28 are movable relatively to allow a surgeon access to the body cavity and can be biased together to seal the cavity 2 when not in use. A sleeve 30 connected to the web 6 covers the shell 28 and passes into the cavity 2 and is terminated in the cavity 2 by a distal valve 31 having a mechanical seal 32. It will also be understood that the web 6 may equally be provided by an anchoring ring.

In use, the parts of the foam shell 28 are separated as before by the surgeon's hand or instrument and the foam moulds the shape of the inserted object to prevent loss of pressure. The inserted object then travels through the sleeve 30 to the distal valve 31 inside the cavity 2 and opens the mechanical seal 32. When the task has been completed the inserted object is removed and the mechanical seal 32 being so biased closes. The pressure in the cavity 2 is such during procedures of this type to close the sleeve 30 along its length as the object is removed and a final seal is provided by the foam shell 28 decompressing when the object has been removed.

The use of a foam shell has a number of advantages over known systems. For example, trauma at the incision is minimised as shock associated with downward pressure when inserting the surgeon's hand is largely absorbed by the foam. Tenting is eliminated as the foam shell reduces the volume of gas in the proximal end of the sleeve. The foam may also be used to absorb liquids such as blood in a hygienic manner and may reduce the effect of blood and body fluids on the anchoring ring. Furthermore it is envisaged that the lifting action of the foam may be used to retract tissue or for creating additional anchoring forces or between the distal valve and the abdominal wall. The cell may also be formed in any suitable manner to allow for the removal of operative tissue during the course of an operation whether or not pneumoperitoneum has been established.

It will be noted that the sleeve and valve may incorporate means for preventing the sleeve returning through the incision accidentally. These means may include but are not limited to an angled flap or flaps on the distal valve, tensioning means in the sleeve such as weld lines or a physical connection to a body part including the abdominal wall.

It will be understood that the foam shell may also be provided as a single block, defining a passageway therein, to allow communication between the exterior and the cavity.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention as defined in the appended claims.

CLAIMS:

1. A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin; and

sealing means connected between the body cavity engagement means and the fixing means, the sealing means being formed to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould to a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

2. A surgical device as claimed in Claim 1, in which the body cavity engagement means is provided by an anchor ring formed for insertion into the incision.

3. A surgical device as claimed in Claim 1 or Claim 2, in which the fixing means is provided by an adhesive web or fixing ring.

4. A surgical device as claimed in any one of the preceding claims, in which the fixing means has an associated connector ring for receiving additional seals or medical instruments.

5. A surgical device as claimed in any one of the preceding claims, in which the sealing means is provided by a toroid cell formed to engage the incision between the fixing means and the body cavity engagement means.

6. A surgical device as claimed in Claim 5, in which the cell forms a bladder through which the surgeon may access the body cavity, the bladder being filled with a viscous or semi-viscous liquid.

7. A surgical device as claimed in Claim 6, in which the bladder is filled with saline, gel or foam.

8. A surgical device as claimed in Claim 1, in which the sealing means incorporates a foam shell formed for covering the incision.

9. A surgical device a claimed in Claim 8, in which the foam shell is formed in two parts, or as a single part partially divided along one axis, the parts being movable relatively to allow a surgeon access to the body cavity.

10. A surgical device as claimed in Claim 8 or Claim 9, in which the foam shell is formed by a plurality of individually disengageable layers, so that the surgeon can adjust the height of the foam shell in response to particular needs by adding or removing foam layers whereby a single device may be used on abdomens of varying thickness, enhancing flexibility of application.

11. A surgical device as claimed in Claim 10, in which the rigidity created by the induced gas and foam apron allows for hand insertion and withdrawal without the aid of an assistant or requiring the surgeon to use the other hand.

12. A surgical device as claimed in Claim 10 or Claim 11, in which the external valve created by the inclusion of a foam shell is enhanced by the pressure of the induced gas passing up between the double walled tube and acting to force the opposing faces of film together outside the patients abdominal cavity.

13. A surgical device as claimed in any one of the preceding claims in which the sealing means further incorporates a distal valve for insertion into the body cavity.

14. A surgical device as claimed in Claim 13, in which the distal valve includes a mechanical seal.

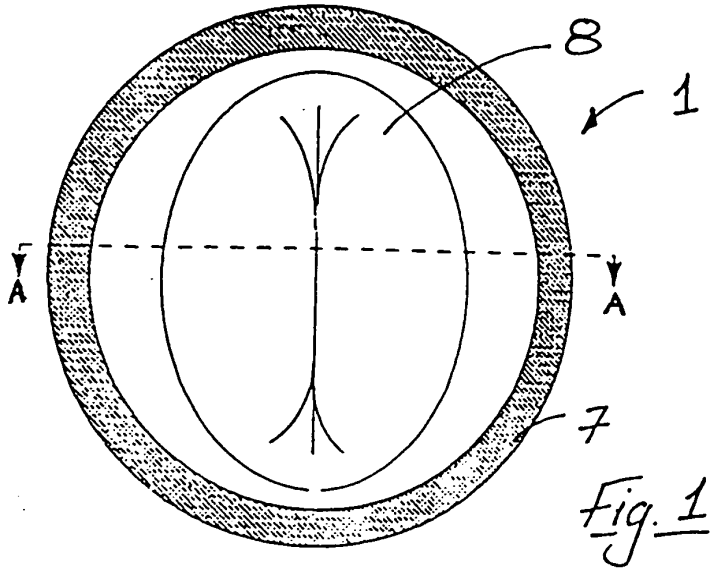

Fig. 1

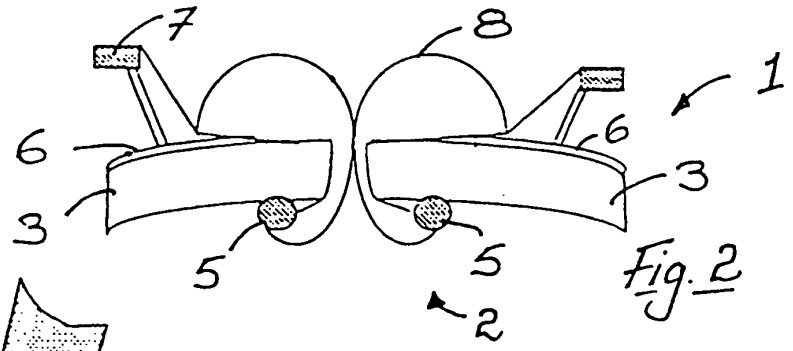

Fig. 2

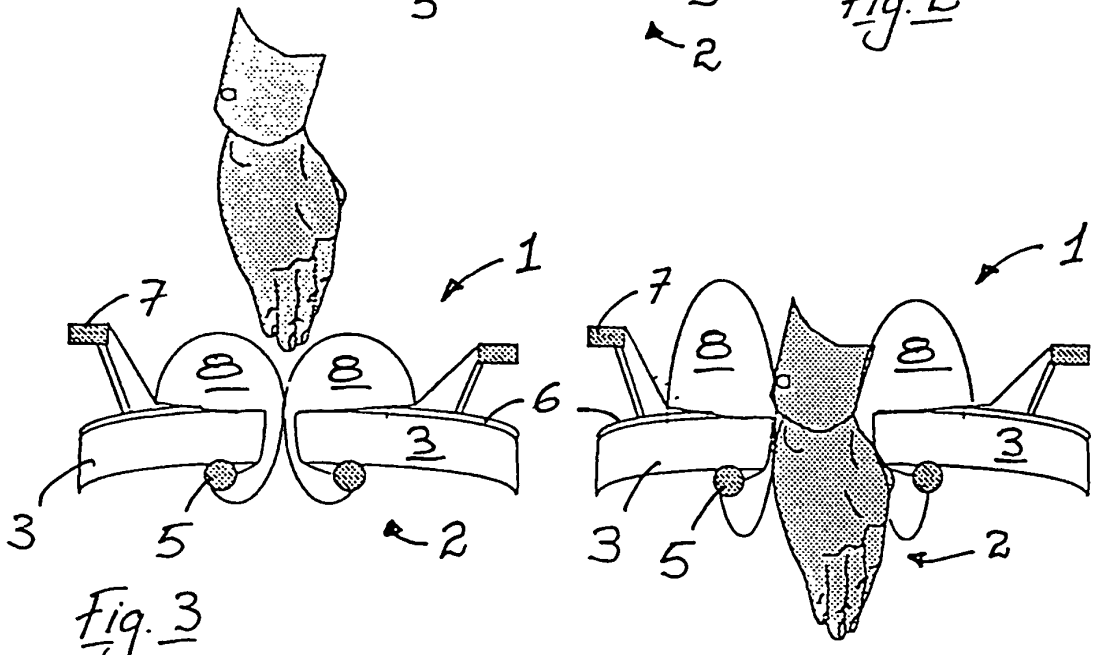

Fig. 3

Fig. 4

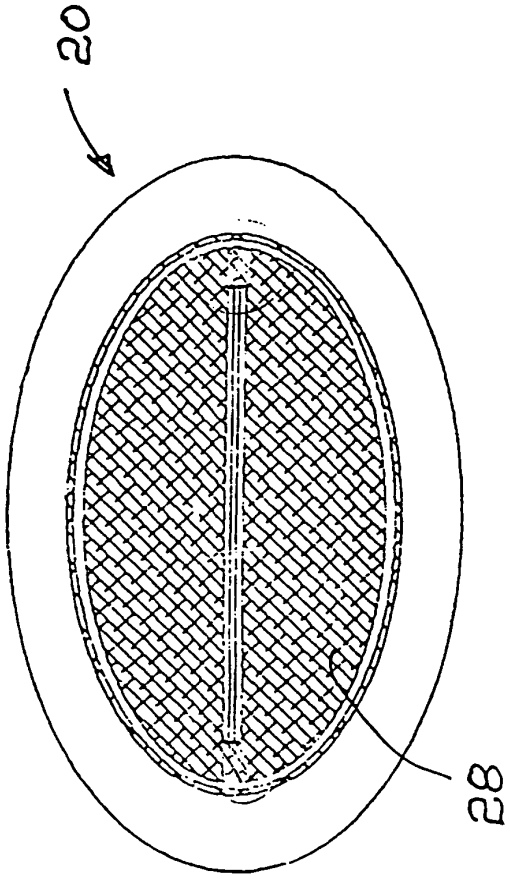

Fig. 5

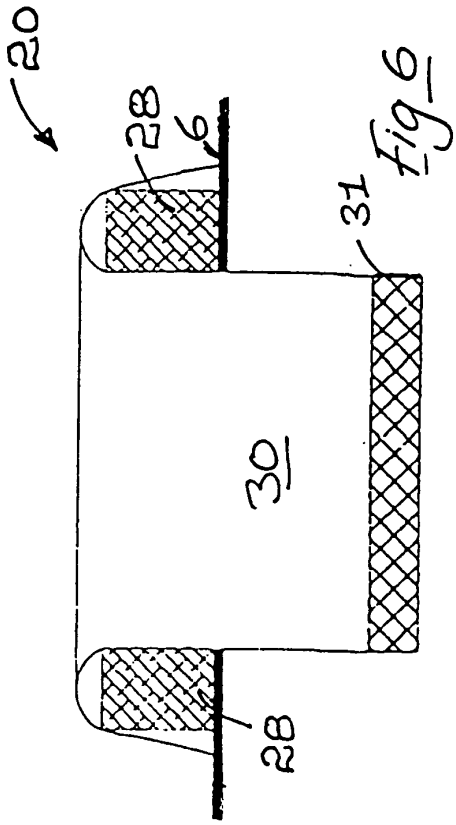

Fig. 6

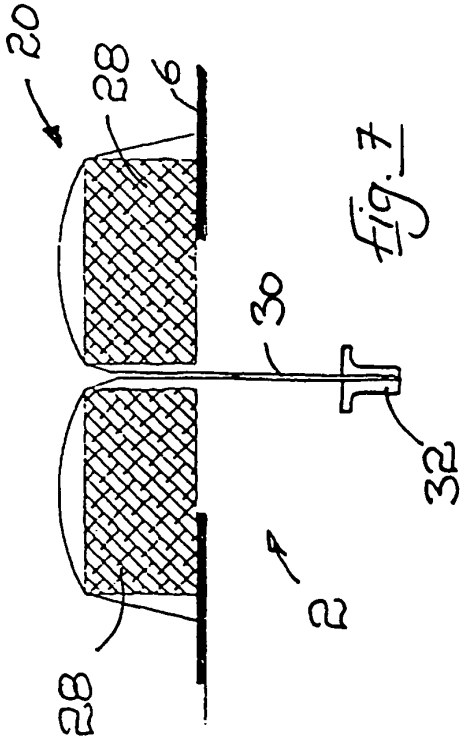

Fig. 7